VDH VIRGINIA DEPARTMENT OF HEALTH

Remdesivir Use, Receipt, and Allocation in Virginia
Frequently Answered Questions
May 13, 2020

What is remdesivir?

Remdesivir is an investigational drug being studied as a treatment for COVID-19. Gilead Sciences Inc., the pharmaceutical company that makes remdesivir, received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration on May 1, 2020 to allow the medication to be utilized by hospitalized COVID-19 patients with severe disease.

Why did the FDA authorize emergency use of remdesivir?

The National Institutes of Health and Gilead Sciences worked together to conduct a randomized controlled clinical trial of the investigational drug in hospitalized patients. Preliminary results suggested that remdesivir was associated with faster recovery, although the data was not sufficient to determine if the drug was associated with lower mortality. Preliminary results indicate that patients who received remdesivir had a 31% faster time to recovery than those who received placebo ($p<0.001$). Specifically, the median time to recovery was 11 days for patients treated with remdesivir compared with 15 days for those who received placebo. Results also suggested a survival benefit, with a mortality rate of 8.0% for the group receiving remdesivir versus 11.6% for the placebo group ($p=0.059$).

Which types of patients in hospitals can receive remdesivir?

The emergency use authorization of this unapproved product is for the treatment of suspected or laboratory confirmed COVID-19 cases in adults and children hospitalized with severe disease. Severe disease is defined as patients with a low oxygen saturation ($SpO2 \leq 94\%$ on room air) or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation.

How do states get remdesivir?

Gilead Sciences has donated a supply of this medication which has been distributed by the U.S. Department of Health and Human Services to specific hospital systems and states. It is expected that future shipments of remdesivir under the EUA will only be distributed to states for further allocation within each state.

How much remdesivir has Virginia received?

VDH received an allotment of 10 cases on Monday, May 11. Each case includes 40 vials of medication, with 100 mg of remdesivir in each vial. Ten cases of this medication equates to treatment of an estimated 36 patients using a 10 day course of this drug. A prior shipment of 33 cases of remdesivir, as determined by the White House Taskforce/U.S. Health and Human Services, was provided to Inova Health System in a separate package.

What is the plan for distributing remdesivir in the Commonwealth?

The VDH Division of Pharmacy Services is responsible for receiving, storing, and distributing this remdesivir, along with any future shipments of the drug, in accordance to an appropriate distribution plan, taking into account community-level needs and the limited supply with input from the Virginia Emergency Support Team Unified Command, Virginia Hospital and Healthcare Association (VHHA) and the Governor's office.

VDH is working with the Virginia Hospital & Healthcare Association (VHHA) to identify hospitals that are able to use medication doses provided in accordance with the U.S. Food and Drug Administration (FDA) Emergency Use Authorization issued on May 1st. The distribution of the initial remdesivir to acute care hospitals will be determined by a random selection model (lottery system) based on confirmed COVID-19 positive patients and a hospital's ability to support the clinical use of remdesivir as confirmed by an attestation form back to the state. Since Inova Health System received an initial supply directly from HHS, they were not included in the lottery to receive further medications from the state's initial disbursement, but will be included in future disbursements by the state.

I've read that remdesivir is also available to patients through clinical trials. How do I find out about those research studies?

There are ongoing clinical trials evaluating the effectiveness of remdesivir in treating COVID-19. Various Virginia hospitals are participating. For more information, please visit clinicaltrials.gov.